

WHAT IS CLAIMED:

1. A stable aqueous pharmaceutical formulation comprising a therapeutically effective amount of an antibody not subjected to prior lyophilization, a buffer maintaining the pH in the range from about 4.5 to about 6.0, a surfactant and a polyol.
- 5 2. The formulation of claim 1 which is isotonic.
3. The formulation of claim 1 which is stable at a temperature of about 2-8°C for at least one year.
4. The formulation of claim 1 which is stable following freezing and thawing of the formulation.
- 10 5. The formulation of claim 1 which is stable at about 30°C for at least one month.
6. The formulation of claim 1 wherein the polyol is a nonreducing sugar.
7. The formulation of claim 6 wherein the nonreducing sugar is trehalose.
8. The formulation of claim 6 wherein the nonreducing sugar is sucrose.
9. The formulation of claim 1 wherein the antibody is an antibody fragment.
- 15 10. The formulation of claim 9 wherein the antibody fragment is a F(ab')₂.
11. The formulation of claim 1 wherein the antibody binds CD18.
12. The formulation of claim 1 wherein the buffer maintains the pH in the range from about 4.8 to about 5.5.
13. The formulation of claim 1 wherein the antibody concentration in the formulation is 20 from about 0.1 to about 50 mg/mL.
14. The formulation of claim 1 wherein the surfactant is a polysorbate.
15. The formulation of claim 1 wherein the antibody binds CD20.
16. The formulation of claim 15 wherein the buffer is histidine or acetate.
17. The formulation of claim 16 wherein the histidine or acetate is present in an 25 amount of about 5-30 mM.
18. The formulation of claim 15 further comprising a preservative.
19. The formulation of claim 18 wherein the preservative is benzyl alcohol.
20. The formulation of claim 15 wherein the antibody is present in an amount of about 30-50 mg/mL.
- 30 21. The formulation of claim 20 wherein the buffer is about 20-30 mM acetate at about pH 5, the polyol is trehalose in an amount of about 1-15% w/v, the surfactant is polysorbate in an amount of about 0.01-0.03%, and wherein the formulation further comprises benzyl alcohol in an amount of about 0.5 to 1%.

22. An article of manufacture comprising a container holding a stable aqueous pharmaceutical formulation comprising a therapeutically effective amount of an antibody not subjected to prior lyophilization, a buffer maintaining the pH in the range from about 4.5 to about 6.0, a surfactant and a polyol.

5 23. A method for stabilizing an antibody in an aqueous pharmaceutical formulation by combining a therapeutically effective amount of an antibody not subjected to prior lyophilization, a buffer maintaining the pH in the range from about 4.5 to about 6.0, a surfactant and a polyol.